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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,370	10/07/2003	James G. Dobson JR.	07917-045004	4664

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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,370	DOBSON ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,56 and 59-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54, 56, and 59-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Response filed on 06/13/05. Applicants have amended claim 54 and 56 and cancelled claims 55, 57, 58, and 67-73. Claims 54, 56, and 59-66 are pending in the instant application.

Claim Objections

Previously, claims 57 and 58 were objected as being duplicates of claims 55 and 56. However, Applicants have cancelled claims 57 and 58 rendering this objection moot. Thus, the claims objection is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54, 56, and 59-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,645,513. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the sets of claims are directed to a method of enhancing the skin condition by topically applying adenosine or adenosine analog in an amount effective to enhance the condition of the skin. The patented claims recite the effective amount of adenosine or its analogs between 10^{-3} to 10^{-7} M. The application claims recite the amount of adenosine analog from 10^{-4} to 10^{-7}, which falls within the claimed range of the patented. Further, instant dependent claim 65 recite specific adenosine analogs, whereas the patent does not. However, because the amount of adenosine and its analogs are being employed for achieving the same end result i.e., a method of enhancing the condition of an unbroken skin by reducing one or more of wrinkling, roughness, dryness or laxity of skins it would have been obvious for a skilled artisan at the time of the instant invention to practice the claimed method by employing the composition of patented claims. Therefore, this is an obviousness double patenting rejection.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argued that the '513 patent does not recite the use of adenosine analogs or even an obvious variation of the invention claimed in the '513 patent. The Examiner finds this argument unpersuasive, because the use of adenosine analogs is obviously disclosed in the '513 patent. The use of "adenosine analogs" are disclosed in the abstract, more than ten times in the specification, and the title of the '513 patent is "Treatment of Skin with Adenosine or Adenosine Analog".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 54, 56, 59-62, and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,998,423 to Manneth et al (hereafter '423).

'423 teaches compositions comprising adenosine, cyclohexyladenosine or cyclopentyladenosine and their use for the modulation of melanin production in the skin and hair and in enhancing the tanning process and providing protection for the skin against UV radiation (see col. 1, lines 7-13, col. 2, lines 44-63,' col. 5, lines 10-18). Enhancing the tanning process on the skin, taught by '423, reads on the enhancing the

condition of non-diseased skin. With respect to claimed amounts of adenosine agonists, '423 discloses preferred amounts of adenosine receptor antagonists (which is same as adenosine agonists), in the range of 100nM or 10nM, which is within the claimed range (col. 3, lies 8-12 and col. 4, lines 7-17).

'423 discloses various formulations of the composition including topical formulation containing various thickeners, castor oil and other additives (Co1s. 5 and 6 and examples 2 and 3) that read on the claimed conditioning agents. With respect to the skin graft claimed, '423 tested the adenosine agonists in neonatal foreskins (col. 7, example 1, lines 5-37), which are nothing but skin grafts. Further, '423 disclose that increased cAMP causes increase in tyrosinase activity, which in turn increases melanogenesis. However, '423 do not show that their adenosine agonists show any increase in cell proliferation. Thus, the instant claims are anticipated by '423.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argued that enhancing the tanning process (i.e., increasing melanin) and protecting the skin against UV rays are not the same as enhancing the condition of broken skin by reducing wrinkles, roughness, dryness or laxity. However, in Bilia et al (US 5,486,353), this prior art disclosed "with the formation of melanin and thickening of the horny cell layer, the skin builds up its own natural protection against the sun's rays. In healthy skin and in healthy cells, these reactions proceed in an optimal fashion. In prematurely aged skin, which is damaged as a consequence of repeated exposure to the sun, they are reduced. The skin's capability of withstanding external environmental factors such as water and wind is also reduced. Stressed skin

shows symptoms such as wrinkles, dry, rough and tanned farmer's skin as well as lentigo senilis." Thus, not only does the melanin beautify (enhance) the skin by tanning, the melanin would also protect the skin from wrinkles, dryness, and roughness.

Applicants further argued that the "numbers recited in the '423 patent at column 4, lines 7 to 17 are in fact K_i values, which are measures of activity level with respect to adenosine receptor binding assay, and not concentrations to be administered." On closer examination, the Examiner finds that Applicants are correct regarding the numbers on column 4 represented K_i values. However, the numbers in the '423 patent at column 5, lines 48 to 56 recited the correct concentrations to be administered is 0.001% to 20%, which encompass Applicants' concentration of 0.006% as asserted by Applicant on page 7.

Additionally, Applicants asserted that the Examiner cannot merely assume that the '423 patent methods do not cause an increase in dermal cell proliferation when the '423 patent does not show if the adenosine agonists caused any increase in cell proliferation. Examiner finds Applicants argument unpersuasive, because the Applicants' pending claims and patent '423 both incorporate adenosine analogs to enhance the skin. Any reasonable person would recognize that the same chemical compounds would have the same chemical properties (or mechanism of actions). For example, at sea level, the chemical compound H_2O has the chemical property of boiling at 100°C. If a prior art does not disclosed that a chemical compound H_2O boils at 100°C at sea level, a reasonable person could apply the logical reasoning described

above and correctly deduce that the prior art's chemical compound H_2O would also boil at 100°C.

In this case, if an adenosine or adenosine analog could enhance the skin without increasing dermal cell proliferation, a reasonable person could deduce that another adenosine or adenosine analog could enhance the skin without increasing dermal cell proliferation. Nevertheless, Applicants contend this is not enough. Applicants have suggested that more proof is needed and that the burden of proof should be placed on the Patent Office. However, it would be too costly and burdensome for the Patent Office, which has limited resources, to have the burden of proving on every application that the same chemical compounds would have the same chemical properties. If Applicants disagree with this logical and scientific reasoning, then the burden of proof should be on the Applicants to prove why the logical and scientific reasoning is incorrect.

Thus, the 102(e) rejection still stands for claims 54, 56, 59-62, and 65.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54, 56 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,256,649 to Le Fur ('649).

'649 discussed above teach a method of treating aged skin by applying a composition comprising ATP or an ATP generating system, betaine, magnesium and potassium salt. The composition further comprises the claimed conditioners. While '649 does not specify the amounts of ATP in terms of molar percentages, '649 suggests ATP at 0.45 to 4.5% (col. 3 table), it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an optimum amount of ATP in the cosmetic composition of '649 with an expectation to achieve the desired effect of combating the external factors so as to prevent premature aging of the skin because '649 suggests that ATP or ATP generating system in the composition slows down aging by maintaining optimum fluidity of the skin cell membrane and improving the condition of the skin (col.5).

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that "there is simply no suggestion in the '649 patent that either the claimed methods or the '649 methods would work at such low concentrations as Applicants are now claiming." However, the amount of adenosine analog in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of adenosine analog to best achieve the desired results. Furthermore, the '423 patent disclosed that the concentrations could typically be in the range from about 0.001% to 20% (col. 5, lines 48-56). Therefore, an ordinary person skilled in the art would have been

motivated to experiment with concentrations lower than 0.001%, because the less amount of adenosine analog used, the cheaper the product. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of adenosine analog concentration would have been obvious at the time of Applicant's invention.

Applicants further argue that the "the Applicants' claimed methods are believed to stimulate receptor-mediated physiological responses on the skin cells to enhance protein synthesis, cell size, etc., to enhance the condition of the skin. These are entirely different effects than the betaine/ATP mixture proposed in the '649 patent to increase membrane fluid. Examiner finds this argument unpersuasive, because as stated above the same chemical compound would have the same chemical properties and mechanism of actions. If a prior art states water boil at 100°C and another prior art states water freezes at 0°C, an ordinary person skilled in the art could logically deduce water has both of these properties. ATP has many mechanisms of action and functions in the human body. The prior art and Applicants' invention method comprise of topically apply an ATP or adenosine analog composition on the skin; therefore, an ordinary person skilled in the art could logically deduce this ATP or adenosine analog composition has both mechanisms of action.

Claims 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,256,649 to Le Fur as applied to claims 54, 56 and 66 above, and further in view of US 5,770,582 to von Borstel et al (hereafter '582) OR

'649 fail to teach angiogenic factor and the skin graft as claimed.

'582 teach deoxyribonuclosides such as 2'-deoxyadenosine for accelerating the healing of wounds, cuts, and abrasions and to ameliorate the effects of aging (see abstract, col. 1, field of the invention, col. 5, 6). '582 teaches angiogenic factors (col. 8, lines 24), growth factors such as fibroblast growth factor (col.7 and 8) and other additives for topical application (col. 7, lines 19 - 65 and col. 8). '582 teaches that glycosaminoglycans, angiogenic factors, peptide growth factors such as, bFGF, PDGF etc., may be added to the compositions containing 2-deoxyribonucleosides (col. 8, lines 24-31). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate peptide growth factors or glycosaminoglycans, all of which read on angiogenic factors of the instant claims, in the skin treating composition of '649 with an expectation to enhance skin condition and also achieve quick wound healing effect on the skin.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that claim 62 depends from claim 54, and is thus patentable for at least the same reasons as claim 54 as argued by Applicants. However, claim 54 is still unpatentable as discussed above by Examiner.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,998,423 to Manneth et al (hereafter '423) as applied to claims 54, 56 and 66 above, and further in view of US 5,785,978 to Porter ('978).

'423 fail to teach a transdermal patch. '978 teach transdermal patches comprising skin care compositions wherein the compositions comprise active agents such as vitamins or moisturizers for applying and protecting skin from wrinkling, yellowing, dryness or other aging conditions (col. 1 and col. 6). '978 do not specifically teach the claimed active agents. However, it would have been obvious for one for one of an ordinary skill in the art at the time of the instant invention to prepare the composition of '423 containing adenosine analogs in the form of a transdermal patch and apply it to skin, because '978 suggests that patches can be conveniently applied to the desired target site, improve the oxygen supply to the applied site and also that the evaporation of the composition is minimal from the patch. Accordingly, a skilled artisan would have expected to achieve the added advantages of improved oxygen supply and minimal evaporation with the patches containing the composition of '423, while treating skin dryness, wrinkles, etc.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that claims 63 and 64 are patentable for at least the same reasons as claim 54, from which these claims depend. However, claim 54 is still unpatentable as discussed above.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,256,649 to Le Fur as applied to claims 54 and 56 above, and further in view of US 5,785,978 to Porter ('978).

'649 fail to teach a transdermal patch. '978 teach transdermal patches comprising skin care compositions wherein the compositions comprise active agents such as vitamins or moisturizers for applying and protecting skin from wrinkling, yellowing, dryness or other aging conditions (col. 1 and col. 6). '978 do not specifically teach the claimed active agents. However, it would have been obvious for one for one of an ordinary skill in the art at the time of the instant invention to prepare the composition of 1649 containing ATP in the form of a transdermal patch and apply it to skin, because '978 suggests that patches can be conveniently applied to the desired target site, improve the oxygen supply to the applied site and also that the evaporation of the composition is minimal from the patch. Accordingly, a skilled artisan would have expected to achieve the added advantages of improved oxygen supply and minimal evaporation with the patches containing the composition of '649, while treating skin dryness, wrinkles, etc.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that claims 63 and 64 are patentable for at least the same reasons as claim 54, from which these claims depend. However, claim 54 is still unpatentable as discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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